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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/207,649	12/08/1998	SUSAN LINDQUIST	17481-004001	7099
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EXAMINER CHERNYSHEV, OLGA N				
ART UNIT 1649		PAPER NUMBER		
NOTIFICATION DATE 02/11/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

09/207,649

Applicant(s)

LINDQUIST, SUSAN

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 7-20, 22 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-11, 14-20, 22 and 37 is/are rejected.
- 7) ☒ Claim(s) 3, 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-884)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2008 has been entered.
2. Claims 1, 3, 7-20, 22 and 37 are under examination in the instant office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on December 22, 2008 have been fully considered but are not persuasive for the following reasons.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1, 7-11, 14-20, 22 and 37 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in section 6 of Paper mailed on March 29, 2007 and section 6 of Paper mailed on November 21, 2007.

Applicant traverses the rejection by referring to Example 16 of the Written Description Training Materials, pp. 2-3 of the Response. Applicant states, “the sample claim analyzed therein relates to a novel method of introducing “a nucleic acid” into “mammalian cells.” Although the specification describes the structure of only one nucleic acid (the beta-galactosidase gene) and reduces to practice only one species within the claimed genus, the sample process claim nonetheless satisfies the written description requirement because one of ordinary skill in the art would recognize the inventor to have been in possession of the claimed method at the time of filing”. Applicant’s argument has been fully considered but not found to be persuasive. The Examiner finds no analogy between the Example 16, wherein the process required possession of “mammalian cells”, which one of skill in the art at the time of invention would have no problem of envisioning, to be transfected with “a nucleic acid”, the term clearly understood by a skilled worker, and the limitation employed by the instant claims – “mammalian aggregate-prone amyloid protein”. As fully explained in the previous office actions of record, the term encompasses a genus of unknown number of species with no specific conserved identified structure or any feature that is explained by Applicant and conveyed to the skilled practitioner to clearly indicate the possession of the “mammalian aggregate-prone amyloid protein(s)”.

At p. 3 of the Response, Applicant argues that the instant case has no analogy with the *Lilly* case law because, “[t]he claims of the present application are not directed to nucleic acids, proteins, or any other composition. Instead, the present application contains claims to screening methods”. Applicant further submits that the recited genus of mammalian amyloid is adequately described because, “[t]he person of ordinary skill in the art would understand these well-characterized amyloid-forming proteins, including huntingtin, atrophin-1, ataxins, androgen

receptor, tau, and a-synuclein, to be encompassed by the generic claim term "mammalian aggregate-prone amyloid protein." The term "mammalian" merely requires that the "aggregate-prone amyloid protein" be mammalian in origin. The skilled biologist would have no difficulty determining whether or not a given aggregate-prone amyloid protein is "mammalian" in origin". Applicant's argument has been given a careful consideration but is not persuasive for the reasons that follow.

While it is true that the instant claims 1, 7-11, 14-20, 22 and 37 are directed to methods employing "mammalian aggregate-prone amyloid protein" and not to the product, "mammalian aggregate-prone amyloid protein" itself, the methods explicitly require possession of the product as part of practicing the invention. The Examiner maintains that at the time of invention the instant specification failed to describe the entire genus of proteins encompassed by the term "mammalian aggregate-prone amyloid protein". Compliance with the written description requirement is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). If at the time of invention Applicant was in possession of the genus of mammalian amyloid proteins, it should not be a problem to describe in clear terms as how these proteins look like so that a skilled practitioner would have a full understanding as what protein is suppose to be a part of the chimera of the transfected yeast cells, see claim 1, for example. As fully explained in the previous office action of record, the specification cannot refer one skilled in the art to an assay to research, discover and identify for themselves what Applicant has invented.

Further, in Paper mailed on November 21, 2007, the Examiner has cited *University of Rochester*, in which the court held that the disclosure of screening assays and general classes of

compounds was not adequate to describe compounds having the desired activity without disclosure of *which* peptides, polynucleotides, or small organic molecules have the desired characteristic; the court found claims directed to methods using those compounds lacking written description, see pp. 6-7. Thus, Applicant's arguments that claiming a method and not a product would satisfy the written description requirement under 112, first paragraph are not persuasive.

For reasons of record fully explained in the previous communications of record and reasons above, the instant rejection is maintained.

Allowable Subject Matter

7. Claims 3, 12 and 13 are objected to for being dependent from rejected claims but would be allowable if rewritten in independent format to include all the limitations of the base claim(s).

Conclusion

8. No claim is allowed.

9. This is a request for continued examination of applicant's earlier Application No. 09/207,649. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

February 05, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649